

## P, ENT COOPERATION TREAT

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C. 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day month year) 25 October 1999 (25.10.99)	
<b>International application No.</b> PCT/US99/01823	<b>Applicant's or agent's file reference</b> MGH-0002
<b>International filing date</b> (day/month/year) 28 January 1999 (28.01.99)	<b>Priority date</b> (day month year) 30 January 1998 (30.01.98)
<b>Applicant</b> WANDS, Jack et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

25 August 1999 (25.08.99)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b> Jean-Marie McAdams
Facsimile No.: (41-22) 740 14 35	Telephone No.: (41-22) 338 83 38

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: MARK DELUCA  
WOODCOCK WASHBURN KURTZ MACKIEWICZ  
& NORRIS LLP  
ONE LIBERTY PLACE - 46TH FLOOR  
PHILADELPHIA, PENNSYLVANIA 19103

**RECEIVED**  
JUN 05 2000  
Woodcock Washburn Kurtz  
Mackiewicz & Norris LLP

## PCT

### NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

**31 MAY 2000**

Applicant's or agent's file reference  
MGH-0002

#### IMPORTANT NOTIFICATION

International application No.  
PCT/US99/01823

International filing date (day/month/year)  
28 JANUARY 1999

Priority Date (day/month/year)  
30 JANUARY 1998

Applicant  
THE GENERAL HOSPITAL CORPORATION

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

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Authorized officer  
DAVID GUZO



Telephone No. (703) 308-0196

# PATENT COOPERATION TREATY


## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MGH-0002	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/01823	International filing date ( <i>day/month/year</i> ) 28 JANUARY 1999	Priority date ( <i>day/month/year</i> ) 30 JANUARY 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant THE GENERAL HOSPITAL CORPORATION		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of <u>4</u> sheets.  <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <u>0</u> sheets.
3.	This report contains indications relating to the following items: <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step or industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>

Date of submission of the demand  25 AUGUST 1999	Date of completion of this report  11 MAY 2000
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231  Facsimile No. (703) 305-3230	Authorized officer  DAVID GUZO   Telephone No. (703) 308-0196

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/01823

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☒ the description:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the sequence listing part of the description:  
pages (See Attached) \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/01823

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. statement

Novelty (N)	Claims <u>7 and 9-34</u>	YES
	Claims <u>1-6 and 8</u>	NO
Inventive Step (IS)	Claims <u>7 and 9-34</u>	YES
	Claims <u>1-6 and 8</u>	NO
Industrial Applicability (IA)	Claims <u>1-34</u>	YES
	Claims <u>NONE</u>	NO

## 2. citations and explanations (Rule 70.7)

Claims 1-6 and 8 lack novelty under PCT Article 33(2) as being anticipated by Selby et al. or Houghton et al.

Applicants, Selby et al. and Houghton et al. all recite recombinant nucleic acid molecules comprising a nucleotide sequence encoding a HCV nonstructural protein which can be NS3, NS4 or NS5 or a fusion protein comprising said proteins or a fragment encoding at least 50 amino acids of said nonstructural proteins. Applicants, Selby et al. and Houghton et al. also recite that the nucleotide sequences encoding the HCV nonstructural proteins are operably linked to expression regulatory elements operable in human cells and recombinant host cells containing said nucleotide sequences. Selby et al. and Houghton et al. therefore teach the claimed invention.

Claim 7 meets the criteria set out in PCT Articles 33(2) and 33(3) because the art does not teach or fairly suggest the claimed promoter and enhancer elements recited in the context of the HCV nucleic acids.

Claims 9-34 meet the criteria set out in PCT Articles 33(2) and 33(3) because the prior art does not teach or fairly suggest the claimed methods of immunizing humans against HCV infection and pharmaceutical compositions for accomplishing this.

Claims 1-34 meet the criteria set out in PCT Article 33(4), because the claimed invention has industrial applicability in that the claimed recombinant HCV nucleic acids can be used to induce a potentially therapeutic immune response against HCV in human patients.

----- NEW CITATIONS -----

NONE

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

**CLASSIFICATION:**

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): C07H 21/02, 21/04; C12N 15/51, 5/10, 15/85; A61K 39/12, 39/29 and US Cl.: 435/320.1, 366, 370, 455; 424/228.1; 514/44

**I. BASIS OF REPORT:**

This report has been drawn on the basis of the description,  
page(s) 1-23, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the claims,  
page(s) 24-27, as originally filed.  
page(s) NONE, as amended under Article 19.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the drawings,  
page(s) 1-8, as originally filed.  
page(s) NONE, filed with the demand.  
and additional amendments:  
NONE

This report has been drawn on the basis of the sequence listing part of the description:  
page(s) 1-3, as originally filed.  
pages(s) NONE, filed with the demand.  
and additional amendments:  
NONE